REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1, 3-7, 9, 12-17, 21-30, 36-39, 43-46, and 51-64 presently appear in this application, with claims 24-29, 46, 51-58, 60 and 61 withdrawn by the examiner, and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claim 30 is amended to incorporate language from claim 1 and from now cancelled claims 32 and 33.

Claims 15, 21-23, 30 and 43-45 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. This is the enablement rejection referred to as Enablement (1) by the examiner.

Claims 1, 3, 4, 9, 12-17, 21-23, 30, 32, 33, 35-39, 43-45, and 62 have been rejected under 35 U.S.C. §112, first paragraph, as lacking enablement, and this rejection is referred to as Enablement (2) by the examiner.

Claims 5, 6 and 59 have been rejected under 35 U.S.C. §112, first paragraph, as lacking enablement and this rejection is referred to as Enablement (3) by the examiner.

All three enablement rejections are respectfully traversed and are argued together because the enablement issues in the three rejections are very closely related or overlapping.

Attached hereto is an executed 1.132 Declaration that addresses all three enablement rejections in detail. This declaration cites and provides a copy of a review article as an indicia of authority on prior art methods for antigen-loading of APCs and the expectation of an ordinary skilled artisan that the same results would be obtained with these other well known methods as were obtained in the experiments of Example 1 in the present specification. The declaration also addresses the issue of how much work is involved in repeating the process, such as with another haplotype, and explains that, although the work is substantial and tedious, none of it is undue.

Accordingly, as stated in detail in the attached declaration, there is simply no undue experimentation involved, and a person of ordinary skill in the art is fully enabled by the guidance provided in the present specification in combination with this person's knowledge and skill in the art.

Reconsideration and withdrawal of the three enablement rejections are therefore respectfully requested.

Claims 1, 3-7, 9, 12-17, 21-23, and 62-64 have been rejected under 35 U.S.C. §112, first paragraph, as failing to

comply with the written description requirement. This rejection is respectfully traversed.

Applicants do not understand from the examiner's comments if the examiner is still objecting to the negative limitation using the proviso language in claim 1. The examiner appears to refer to some earlier cases that preceded the decision in *In re Johnson* 194 USPQ 196, which is the current standard on negative limitations. MPEP 2173.05(i) specifically teaches the current view of the courts (as followed by the USPTO), stating:

> The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation.

and citing *In re Johnson* for permitting exclusion of alternative elements that were positively recited in the specification from the scope of the claims.

Furthermore, applicants have specifically identified 26 genes that are overexpressed in human colon carcinoma cells from which to screen TAA peptides. The sequences of these 26 genes as well as the encoded amino acid sequences are known in the prior art. Therefore, these 26 genes/encoded proteins are at least representative of the genus of preferred polynucleotides/genes overexpressed in human colon carcinoma cells, if not of the group of genes that one of ordinary skill in the art would consider to be sufficiently overexpressed in human colon carcinoma cells.

With regard to TAA peptides from other haplotypes, these TAA peptides can be obtained with routine experimentation based on the known sequences of the 26 overexpressed genes and their encoded proteins, as discussed in the attached declaration. The seven TAA peptides obtained in Example 1 of the present specification are similarly representative of the genus of TAA peptides encoded by polynucleotides overexpressed in human colon carcinoma cells, which genus is a relatively small finite number.

The Court of Appeals for the Federal Circuit (CAFC) decision in *Enzo Biochem v. Gen-Probe*, 323 F.3d 956, states with regard to written description:

> It is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement. The PTO has issued Guidelines governing its internal practice for addressing that issue. The Guidelines, like the Manual of Patent Examining Procedure ("MPEP"), are not binding on this court, but may be given judicial notice to the extent they do not conflict with the statute. See *Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 n.10, 33 USPQ2d 1823, 1828 n.10 (Fed. Cir. 1995)*. In its Guidelines, the PTO has determined that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Guidelines, 66 Fed. Reg. at

> 1106 (emphasis added). For example, the PTO would find compliance with *§ 112*, P 1, for a claim to an "isolated antibody capable of binding to **[**16]** antigen X," notwithstanding the functional definition of the antibody, in light of "the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature." Synopsis of Application of Written Description Guidelines, at 60, available at http://www.uspto.gov/web/patents/guides.htm ("Application of Guidelines"). Thus, under the Guidelines, the written description requirement would be met for all of the claims of the '659 patent if the functional characteristic of preferential binding to N. gonorrhoeae over N. meningitidis were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed. We are persuaded by the Guidelines on this point and adopt the PTO's applicable standard for determining compliance with the written description requirement.

The specification at pages 20-22 discusses different HLA haplotypes, with specific TAA peptides from different TAA proteins identified for different HLA haplotypes in Table 1, and teaches that just 5-6 different haplotypes would cover about 95% of the world population. The experiments in Example 1 of the specification demonstrate the structure/function relationship between haplotype (MHC class I) HLA-A2.1 and peptides that can fit into the pocket of the HLA-A2.1 haplotype. The structures of different haplotypes (MHC class I molecules) are known in the

art. The present specification, including Example 1 and Table 1, teaches how to correlate structure and function between different haplotypes and different TAA peptides and there are computer models based on the structure/function correlations for some haplotypes. Such a structure/function relationship of the binding of TAA peptides to a specific HLA haplotype (MHC class I molecule) is analogous to the antibody and antigen structure/function relationship, where antibodies bind to a specific antigen, as discussed in *Enzo Biochem v. Gen-Probe* above with regard to satisfying the written description requirement. Accordingly, the written description is satisfied.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 30 and 32 have been rejected under 35 U.S.C. §102(e) as being anticipated by Matsuzaki et al., US20030092037. This rejection is respectfully traversed.

The examiner appears to be under the mistaken impression that claim 32 is a species of the "at least one 8-10 residue TAA peptide" and therefore generic claim 30 embraces all species claims including claim 32. However, the tumor associated antigen (TAA) comprising the amino acid sequence of SEQ ID NO:59, as recited in claim 32, is not a species of the 8-10 residue TAA peptide (which is limited to 8-10 residues and clearly cannot be

the full length TAA comprising SEQ ID NO:59) but rather defines the TAA from which the 8-10 residue TAA is derived. This is clarified by the cancellation of claims 32 and 33 and the amendment to the claim 30.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claim 30 has been rejected under 35 U.S.C. §102(e) as being anticipated by Berger et al., US20030148410. This rejection is respectfully traversed.

Claim 30 is now amended to recite the feature that the at least one 8-10 residue TAA peptide is capable of promoting effective binding to a MHC class I molecule to elicit a CTL response. There is no disclosure of such TAA peptides in Berger and accordingly, Berger cannot anticipate the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claim 32 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is obviated by the cancellation of claim 22.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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